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K960297

510(k) Summary

Device: Mandibular Bone Distractor II

Common Name: External Fixation for Mandible

Classification Name and Reference: 21 CFR 888.3040
Smooth or threaded metallic
bone fixation fastener

Proposed Regulatory Class: Class II

Device Product Code: OR(87) JEC MQN

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The Mandibular Bone Distractor II is intended to be used in the treatment of conditions such as severe mandibular deficiency, post-surgical mandibular defects, or post-traumatic defects of the mandible. This device is intended to function as a stabilizer and mandibular lengthener. Bone transport procedures may also be performed. This device will allow linear and angular distraction of the mandible. The Mandibular Bone Distractor is intended for use in either adults or children.

The Mandibular Bone Distractor II is comprised of two arms, a central body which contains screws to adjust the angular relationship of the arms, and pin clamps. The pin clamps can accept 2mm or 3mm pins.

All of the components of the Mandibular Bone Lengthener II are fabricated from stainless steel.

The Mandibular Bone Distractor II is intended to be sold non-sterile. Sterilization instructions are included in the labeling.

The Mandibular Bone Distractor II is substantially equivalent to products currently in commercial distribution. A list of these equivalent products may be found below.

1. Mandibular Bone Distractor - Howmedica (K945674)
2. Hoffman Mini Fixator - Howmedica (K792561)
3. Monticelli-Spinelli External Fixator - Howmedica (K864403)
4. Mini Lengthening Apparatus - Synthes (K914558)
5. Normed Device - distributed in the United States by Ace Surgical Supply Co. (K# unknown)
6. Wells Johnson Fixation System - Wells Johnson Co. (K945500)

The Mandibular Bone Distractor II is similar to the named devices with respect to intended use, material, design, and operational principles as discussed below:

1. Intended Use: All of the named devices, and the Mandibular Bone Lengthener II, are intended to be used as external fixation devices for the stabilization of bone and bone fragments. The Mandibular Bone Lengthener, Synthes device, Monticelli-Spinelli device, and the subject device are designed to allow distraction of bone segments to achieve lengthening. The Monticelli-Spinelli device, the Normed device, the Wells Johnson device, and the Mandibular Bone Distractor II allow angular distraction. The Synthes Mini-Lengthener, the Normed device, the Mandibular Bone Distractor, the Wells Johnson device, and the Mandibular Bone Distractor II are specifically intended to be used in mandibular applications.
2. Material: The materials used in the manufacture of the Mandibular Bone Lengthener II are different grades of stainless steel. Stainless steel has a long history of successful clinical usage. Stainless steel is used in the manufacture of the Hoffman Mini Fixator, Synthes Mini-Lengthener, and the Mandibular Bone Lengthener.
3. Design: The basic design features of the Mandibular Bone Distractor II, namely, pin clamps that are attached to connecting rods that are adjusted in relation to each other, are the same for all of the named systems. More detailed design features are discussed below:
 - a) Pin clamp: The Mandibular Bone Distractor II, the Hoffman Mini device, and the Wells Johnson device offer pin clamps that accept either 2mm or 3mm pin.
 - b) Threaded arms: The Mandibular Bone Distractor II, the Normed device, and the Synthes Mini-Lengthener have arms, or connecting rods that are threaded to accept a pin clamp.

- c) **Screw Mechanism:** The Mandibular Bone Distractor II, the Mandibular Bone Distractor, the Synthes Mini Lengthener, the Normed device, and the Monticelli-Spinelli device all have screw mechanisms that the surgeon adjusts to control either the relationship of one pin clamp to another, or the relationship of one connecting rod (or arm) to another.

4. **Operational Principles:** The basic operational principles for the Hoffman Mini-Fixator, Synthes Mini Lengthener, the Mandibular Bone Distractor, Normed device, the Wells Johnson device and the subject device are similar - namely site preparation, pin placement, and device construction. The bone distraction procedure is similar for the Mandibular Bone Distractor II, the Synthes Mini-Lengthener, the Normed device, the Wells Johnson device, and the existing Mandibular Bone Distractor.